

PHARMACY SERVICES AGREEMENT

THIS First **PHARMACY SERVICES AGREEMENT** (this “Agreement”) dated 01/01/2023, (the “Effective Date”) between County of Monterey, for services to Monterey County Health Department’s Clinic Services Bureau, whose billing/principal place of business is 1615 Bunker Hill Way, Suite 140, Salinas, CA 93906 (“Covered Entity”), and **PMQ Group, LLC dba Avita, on behalf of its subsidiaries**, whose finance office is located at **10604 COURSEY BLVD, BATON ROUGE, LA 70816** (together, “Pharmacy”) (Covered Entity and Pharmacy together referred to herein as the “Parties” or individually as a “Party”).

WHEREAS, Covered Entity is a “covered entity” as defined in Section 340B of the Public Health Service Act (“Section 340B”), and, as such, is eligible to purchase, for use by Eligible Patients (as hereinafter defined), certain outpatient drugs at reduced prices pursuant to the 340B Drug Purchasing Program (“340B Drugs”) from Covered Manufacturers (as hereinafter defined);

WHEREAS, Pharmacy has unique expertise in developing and operating specialty pharmacies and maximizing the benefits of the 340B Drug Purchasing Program; and

WHEREAS, Pharmacy will serve the Parent and Child sites (where applicable) of the Covered Entity as listed in/on HRSA’s Office of Pharmacy Affairs Database/Website including but not limited to the following 340B ID(s): CHC33795-00; CHC33795-01; CHC33795-02; CHC33795-03; CHC33795-04; CHC33795-05; CHC33795-06; CHC33795-07; CHC33795-08; CHC33795-09 and at the Covered Entity site addresses listed on Exhibit A; and

WHEREAS, Covered Entity desires to engage Pharmacy to provide Contract Pharmacy Services (as hereinafter defined), and Pharmacy desires to accept such engagement, upon the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants contained in this Agreement, and other good and valuable consideration, the Parties hereby agree as follows:

A. **DEFINITIONS**. As used in this Agreement, the following terms shall have the following meanings:

- 1.1 “340B Drugs” has the meaning ascribed to it in the second recital above.
- 1.2 “340B Management Fee” has the meaning ascribed to it in Exhibit B.
- 1.3 “Agreement” has the meaning ascribed to it in the preamble above.
- 1.4 “Assistance Program” has the meaning ascribed to it in Section 2.6 below.
- 1.5 “Confidential Information” has the meaning ascribed to it in Section 6.2 below.

- 1.6 “Contract Pharmacy Services” has the meaning ascribed to it in Section 2.1 below.
- 1.7 “Covered Drugs” means the prescription drugs listed in the most recent Section 340B Drug Formulary published by DHHS, as updated from time-to-time, that are purchased by Covered Entity and delivered to Pharmacy pursuant to the 340B Drug Purchasing Program and this Agreement. The Parties agree that upon mutual agreement Covered Drugs may be added or removed from coverage under this Agreement.
- 1.8 “Covered Entity” has the meaning ascribed to it in the preamble above.
- 1.9 “Covered Manufacturer” means a drug manufacturer that has signed a drug purchasing agreement with DHHS.
- 1.10 “Damages” has the meaning ascribed to it in Section 7.2 below.
- 1.11 “DHHS” means the United States Department of Health and Human Services.
- 1.12 “Dispensing Fee” has the meaning ascribed to it in Exhibit B.
- 1.13 “Effective Date” has the meaning ascribed to it in the preamble above.
- 1.14 “Eligible Patient” means an individual meeting all of the following requirements: (i) Covered Entity has established a relationship with the individual such that Covered Entity maintains records of the individual’s health care; (ii) the individual receives health care services from a Qualified Provider; and (iii) the individual receives a health care service or range of services from Covered Entity that is consistent with the service or range of services for which grant funding or federally-qualified health center look-alike status has been provided to Covered Entity.
- 1.15 “HCFA 1500” means the Health Care Finance Administration form used to bill for reimbursement to Medicare.
- 1.16 “Indemnified Parties” has the meaning ascribed to it in Section 7.2 below.
- 1.17 “Indemnifying Party” has the meaning ascribed to it in Section 7.2 below.
- 1.18 “Initial Term” has the meaning ascribed to it in Section 5.1 below.
- 1.19 “NDC” means National Drug Code.
- 1.20 “Party” and “Parties” have the meanings ascribed to them in the preamble above.
- 1.21 “Pharmacy” has the meaning ascribed to it in the preamble above.
- 1.22 “Qualified Provider” means a health care professional who is either employed by

Covered Entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with Covered Entity.

1.23 “Renewal Term” has the meaning ascribed to it in Section 5.1 below.

1.24 “Rule Set Document” shall be any Rule Set Document in place now or in the future between Covered Entity and Avita Drugs, LLC.

1.25 “Section 340B” has the meaning ascribed to it in the second recital above.

1.26 “Standards” has the meaning ascribed to it in Section 6.1 below.

1.27 “Term” has the meaning ascribed to it in Section 5.1 below.

1.28 Unless otherwise defined herein, terms used in this Agreement, whether capitalized or not, shall be defined in a manner consistent with the meanings set forth at 42 U.S.C. § 256b, or as otherwise adopted through regulation or sub-regulatory guidance issued by DHHS.

B. CONTRACT PHARMACY SERVICES.

2.1 Contract Pharmacy Services. Covered Entity hereby engages Pharmacy to provide outpatient contract pharmacy services on its behalf as an agent of Covered Entity for Eligible Patients and Qualified Providers acting on behalf of Eligible Patients with respect to Covered Drugs in accordance with this Agreement and applicable law (“Contract Pharmacy Services”).

2.2 Non-exclusive Provider. Covered Entity is free to engage other pharmacies to provide Contract Pharmacy Services on its behalf in accordance with applicable law.

2.3 Verification of Eligible Patient Status. Pharmacy will administer a Rule Set Document approved by Covered Entity for the determination of Eligible Patients. Covered Entity will furnish a complete and accurate list to Pharmacy of all Qualified Providers and other items outlined in the Rule Set Document and will update these items as needed to reflect any changes.

2.4 Cash or Uninsured Transactions. Prior to dispensing, Covered Entity will notify Pharmacy of patient 340B eligibility through an intake procedure such as a disposition, referral or enrollment form. The agreed process will be covered during development of the Rule Set Document.

2.5 Tracking System. The Parties to this Agreement understand that, pursuant to Section 340B, Covered Entity is liable to the manufacturer and/or drug wholesaler of 340B Drugs in an amount equal to the discount provided by Section 340B pricing in the event that a 340B Drug is sold or otherwise transferred to a person who is not an Eligible Patient. Pharmacy and Covered Entity shall establish and maintain a tracking system suitable to prevent the diversion of Covered Drugs to individuals who are not Eligible Patients. Prior to Pharmacy providing Contract

Pharmacy Services pursuant to this Agreement, Covered Entity shall have the opportunity, upon reasonable notice and during business hours, to examine the tracking system and may require Pharmacy to make any modifications to such system as Covered Entity may, in its reasonable discretion, require. Pharmacy shall permit Covered Entity and its duly authorized representatives to have reasonable access to Pharmacy’s facilities and records during the Term of this Agreement in order to make periodic checks regarding the efficacy of such tracking system. Pharmacy agrees to make any and all reasonable adjustments to the tracking system that Covered Entity advises are reasonably necessary to prevent diversion of Covered Drugs to individuals who are not Eligible Patients.

2.6 Financial Assistance Program (Optional). In order to increase access to 340B Drugs and improve medication compliance for all Eligible Patients, Covered Entity may establish a medication Financial Assistance Program (“Assistance Program”). The Assistance Program would provide financial assistance to Eligible Patients to help offset copay costs for third party covered prescriptions and will be administered solely between Covered Entity and Pharmacy. The Assistance Program would be funded by Covered Entity from the net revenues (program income) received. Covered Entity and Pharmacy will notify Eligible Patients of the availability and advantages of this Program upon an unsolicited expression of financial need by the Eligible Patient.

2.7 Delivery Services. Pharmacy may elect to provide local delivery services to certain patients in its regular course of business. However, should Covered Entity require that this service be expanded in any way, Covered Entity may make a formal written request to Pharmacy. If the Parties mutually agree to expand such services, such delivery services would be offered pursuant to Exhibit C of this Agreement. Such exhibit will not otherwise be applicable.

Expanded Delivery Requested Yes
 No

C. **PARTIES’ OBLIGATIONS.**

3.1 General Duties. Covered Entity and Pharmacy shall perform the duties set forth in Exhibit A of this Agreement, which is incorporated herein by reference. Both Parties agree to timely communications and access to pertinent data and other resources in order for the Parties to fulfill all obligations of this Agreement in a professional and timely manner. Covered Entity shall provide Pharmacy with access to data including, but not limited to, patient demographics, payor information and medical records as necessary to provide the Contract Pharmacy Services. Pharmacy agrees to render the Contract Pharmacy Services in accordance with the professional standards applicable to pharmacy services and in accordance with rules and regulations of the State Boards of Pharmacy. If an issue arises in Pharmacy’s performance of the Contract Pharmacy Services, Covered Entity will notify Pharmacy. Formal meetings with other Avita staff, including account managers and executive leadership, will occur when specific concerns need to be addressed and resolved and/or on an as-needed basis.

3.2 Prohibited Prescriptions. Neither Covered Entity nor Pharmacy will use Covered Drugs (i) to dispense prescriptions paid for by fee-for-service (FFS) or managed (MCO) Medicaid, unless permitted by the Medicaid program or state regulations; or (ii) to dispense prescriptions paid for by any other payor where prohibited.

3.3 Licensure. Throughout the Term of this Agreement, both Parties, their employees and agents, shall maintain any license, permit, certification and/or registration required by state or

federal law to operate their pharmacy business or to perform other responsibilities as contained in this Agreement, and will provide copies of such licensure or other relevant documentation upon request of the other Party.

3.4 Patient Choice. Covered Entity understands and agrees that Eligible Patients may elect not to use Pharmacy for pharmacy services. Covered Entity shall inform each Eligible Patient of his or her ability to independently choose a pharmacy and shall not in any way infer that use of Pharmacy is required. In the event that an Eligible Patient elects not to use Pharmacy, the Eligible Patient may obtain the prescription from the pharmacy provider of his or her choice. Subject to an Eligible Patient's freedom to choose a provider of pharmacy services, Covered Entity will inform Eligible Patients of those situations when they are eligible for a discount on Covered Drugs and advise them that such discount may be obtained only at Pharmacy.

3.5 Prohibition on Resale or Transfer. Neither Party will resell or transfer a 340B Drug to an individual who is not an Eligible Patient. Pharmacy agrees that, in the event of transfer, diversion, or resale of a 340B Drug by Pharmacy in violation of this Agreement, it will pay Covered Entity an amount equal to the Section 340B discount Covered Entity received from the manufacturer. Such payment will be remitted by the Covered Entity to the appropriate manufacturer. Notwithstanding the foregoing, Pharmacy shall have no liability with respect to dispenses and/or replenishment of Covered Drugs to individuals who are not Eligible Patients if such dispenses and/or replenishments are performed in accordance with Section 2.3 hereof.

D. COMPENSATION.

4.1 Payment for Services. Covered Entity agrees to pay Pharmacy for the Contract Pharmacy Services provided hereunder in accordance with Exhibit B of this Agreement, which is incorporated herein by reference.

4.2 No Inducement. Covered Entity and Pharmacy have freely negotiated the payment terms provided herein and neither has offered nor received any inducement or other consideration from the other Party for entering into this Agreement. The compensation to be paid to Pharmacy is consistent with fair market value in arms-length transactions for Contract Pharmacy Services and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the Parties for which payment may be made in whole or in part under traditional Medicaid or other state or federal health care programs.

E. TERMAND TERMINATION.

5.1 Term. This Agreement shall commence as of the Effective Date listed in the preamble and shall continue in effect for a period of **Thirty-Six** (36) months (the "initial term"). Upon expiration of the Initial Term, this Agreement shall automatically renew for additional consecutive terms of Twelve (12) months each (each, a "Renewal Term" and together with the Initial Term, the "Term"), unless either Party gives at least Ninety (90) days' written notice of its intent not to renew this Agreement.

5.2 Termination. This Agreement may be terminated as follows:

- I. by mutual written agreement of the Parties;
- II. by either Party, effective upon written notice to the other party, if the other party materially breaches this Agreement and does not cure such breach within thirty (30) days after receipt of written notice specifying such breach. Either Party knowingly causing the dispensing of a 340B Drug to an individual who is not an Eligible Patient or any other knowing diversion of a 340B Drug shall be deemed to be a material breach.
- III. Both Parties reserve the right to cancel this Agreement, or any extension of this Agreement, without cause, with a thirty day (30) written notice, or with cause immediately.

5.3 Termination Due to Change in Law. The Parties agree that in the event legislation is enacted, regulations are promulgated, official guidance from the state or federal government is provided, and/or a decision of a court is rendered that affects, or may affect, in the opinion of Covered Entity's and/or Pharmacy's legal counsel, the legality of this Agreement or adversely affects the ability of either Party to perform its obligations or receive the benefits intended hereunder, then within sixty (60) days following delivery of written notice by a Party, the Parties will negotiate in good faith an amendment to this Agreement or a substitute agreement that will carry out the original intent of the Parties to the extent possible in light of such legislation, regulation, guidance or decision. In the event that the Parties cannot reach agreement within sixty (60) days following the notice provided in this Section, then this Agreement shall immediately terminate upon written notice of termination from Covered Entity or Pharmacy.

5.4 Return of Records. In the event of termination of this Agreement, and upon the written request of Covered Entity, Pharmacy will provide Covered Entity with copies of all records and materials in its possession related to Covered Entity or Eligible Patients. Pharmacy shall be entitled to retain any and all records and materials as maintained by Pharmacy in its normal course of business.

5.5 Close out Process. In the event of termination of this Agreement, Covered Entity and Pharmacy will true up all outstanding replenishments, partials, and payments through a net transaction settlement to covered entity within sixty (60) days. In the event Covered Entity loses its 340B status, Covered Entity must notify Pharmacy immediately to ensure the close out process is completed prior to the termination date of 340B eligibility. In the event Covered Entity and Pharmacy are unable to perform a close out process prior to 340B termination date, Covered Entity is subject to forfeiture of all remaining settlements and all replenishments, including partial bottles, at retail cost.

5.6 The Covered Entity's payments to Pharmacy under this Agreement are funded by local, state and federal governments. If funds from local, state and federal sources are not obtained and continued at a level sufficient to allow for the County's purchase of the indicated quantity of services, then the CE may give written notice of this fact to Pharmacy, and the obligations of the parties under this agreement shall terminate immediately, or on such date thereafter, as the CE may specify in its notice, unless in the meanwhile the parties enter into a written amendment modifying this Agreement.

F. **CONFIDENTIAL INFORMATION.**

6.1 Patient Identifying Information. Covered Entity and Pharmacy agree to comply with all applicable state and federal laws and regulations regarding confidentiality of patient records, including, but not limited to, the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, and implementing regulations promulgated or to be promulgated by the Secretary of Health and Human Services, (collectively, the "Standards") on and after the applicable effective dates

specified in the Standards. All medical information and data concerning specific patients, including, but not limited to, the identity of the patients, derived from the business relationship set forth in this Agreement shall be treated and maintained in accordance with applicable Standards by both Parties to this Agreement and shall not be released, disclosed, or published to either Party other than as required or permitted under applicable laws.

6.2 Business and Financial Information. The Parties acknowledge and agree that during their association with each other they will be brought into contact with each other's confidential methods of operations, pricing policies, marketing strategies, trade secrets, knowledge, techniques, data and other information about their operations and business of a confidential nature ("Confidential Information") and that such Confidential Information has a special and unique value to each Party. Therefore, neither Party will in any manner, directly or indirectly, disclose or divulge to any person or other entity whatsoever, or use for its own benefit or for the benefit of any other person or entity whatsoever, any of such Confidential Information except as is required for a Party to meet its obligations under this Agreement. Notwithstanding the foregoing, disclosure of this Agreement, including pricing information, may be made if such disclosure is legally required pursuant to the Public Information Act. Upon the expiration or termination of this Agreement for any reason and upon written request by either Party, both Parties shall, where feasible, promptly return to the other or destroy any and all such Confidential Information in its possession or control. Such Confidential Information may be retained as reasonably necessary to support any Contract Pharmacy Services provided pursuant to this Agreement. For purposes of clarity, information generated by Pharmacy while dispensing Covered Drugs to Eligible Patients shall be the confidential information of Pharmacy.

G. INSURANCE.

7.1 Insurance.

A. Evidence of Coverage. Prior to commencement of this Agreement, Pharmacy shall provide a "Certificate of Insurance" certifying that coverage as required herein has been obtained. Individual endorsements executed by the insurance carrier shall accompany the certificate. In addition, Pharmacy upon request shall provide a certified copy of the policy or policies.

This verification of coverage shall be sent to the Covered Entity's Contracts/Purchasing Office, unless otherwise directed. Pharmacy shall not receive approval for services for work under this Agreement until all insurance has been obtained as required and approved by the Covered Entity. This approval of insurance shall neither relieve nor decrease the liability of Pharmacy.

B. Qualifying Insurers. All coverage, except surety, shall be issued by companies which hold a current policy holder's alphabetic and financial size category rating of not less than A- VII, according to the current Best's Key Rating Guide or a company of equal financial stability that is approved by the Covered Entity's Contracts/Purchasing Officer.

C. Insurance Coverage Requirements. Without limiting Pharmacy duty to indemnify, Pharmacy shall maintain in effect throughout the term of this Agreement a policy or policies of insurance with the following minimum limits of liability:

Commercial General Liability Insurance, including but not limited to premises and operations, including coverage for Bodily Injury and Property Damage, Personal Injury, Contractual Liability, Broadform Property Damage, Independent Contractors, Products and Completed Operations, with a combined single limit for Bodily Injury and Property Damage of not less than \$1,000,000 per occurrence.

Business automobile liability insurance, covering all motor vehicles, including owned, leased, non-owned, and hired vehicles, used in providing services under this Agreement, with a combined single limit for Bodily Injury and Property Damage of not less than \$500,000 per occurrence.

Workers Compensation Insurance, if Pharmacy employs others in the performance of this Agreement, in accordance with California Labor Code section 3700 and with Employer's liability limits not less than \$1,000,000 each person, \$1,000,000 each accident and \$1,000,000 each disease.

Other Insurance Requirements. All insurance required by this Agreement shall be with a company acceptable to Covered Entity and issued and executed by an admitted insurer authorized to transact insurance business in the State of California. Unless otherwise specified by this Agreement, all such insurance shall be written on an occurrence basis, or, if the policy is not written on an occurrence basis, such policy with the coverage required herein shall continue in effect for a period of three (3) years following the date Pharmacy completes its performance of services under this Agreement.

Each liability policy shall provide that Covered Entity shall be given notice in writing at least thirty (30) calendar days in advance of any endorsed reduction in coverage or limit, cancellation, or intended non-renewal thereof. Each policy shall provide coverage for Pharmacy and additional insured with respect to claims arising from each subcontractor, if any, performing work under this Agreement, or be accompanied by a certificate of insurance from each subcontractor showing each subcontractor has identical insurance coverage to the above requirements.

Commercial general liability policies shall provide an endorsement naming the County of Monterey, its officers, agents, and employees as Additional Insured with respect to liability arising out of Pharmacy's work, including ongoing and completed operations, and shall further provide that such insurance is primary insurance to any insurance or self-insurance maintained by the County and that the insurance of the Additional Insured shall not be called upon to contribute to a loss covered by Pharmacy's insurance. The required endorsement form for Commercial General Liability Additional Insured is ISO Form CG 20 10 11-85 or CG 20 10 10 01 in tandem with CG 20 37 10 01 (2000). The required endorsement form for Automobile Additional Insured endorsement is ISO Form CA 20 48 02 99.

Prior to the execution of this Agreement by the Covered Entity, Pharmacy shall file certificates of insurance with the Covered Entity's contract administrator and Covered Entity's Contracts/Purchasing Office, showing that Pharmacy has in effect the insurance required by this Agreement. Pharmacy shall file a new or amended certificate of insurance within five (5) calendar days after any change is made in any insurance policy, which would alter the information on the certificate then on file. Acceptance or approval of insurance shall in no way modify or change the indemnification clause in this Agreement, which shall continue in full force and effect.

Pharmacy shall at all times during the term of this Agreement maintain in force the insurance coverage required under this Agreement and shall send, without demand by Covered Entity, annual certificates to Covered Entity's Contract Administrator and Covered Entity's Contracts/Purchasing Office. If the certificate is not received by the expiration date, Pharmacy shall have five (5) calendar days to send the certificate, evidencing no lapse in coverage during the interim. Failure by Pharmacy to maintain such insurance coverage is a breach of this Agreement, which entitles Covered Entity, at its sole and absolute discretion, to terminate this Agreement immediately.

H. **AUDITS.**

8.1 By Secretary or Covered Manufacturers. The Parties understand and agree that they are subject to audit by the Secretary of DHHS and Covered Manufacturers. Covered Entity and Pharmacy agree to cooperate with such audits by retaining auditable records of Covered Drug transactions sufficient to demonstrate compliance. The Parties agree to make available to the Secretary of DHHS and Covered Manufacturers any books, documents, and records in their control relating to the furnishing of Covered Drugs and to comply with applicable provisions of audit guidelines and amendments thereto that may be published from time to time.

8.2 By Covered Entity. Pharmacy agrees to make available to Covered Entity during Pharmacy's normal business hours all necessary books, records, policies and procedures, and patient information, pertinent to this Agreement, upon at least twenty (20) days' written notice should Covered Entity desire to conduct an audit of the activities of Pharmacy as they relate to this Agreement. Covered Entity will contract with an external audit firm to perform an external review and audit for quality assurance of 340B program performance, including contract review. Pharmacy agrees to comply with all reasonable corrective actions recommended by Covered Entity.

I. **MISCELLANEOUS.**

9.1 Independent Contractor. It is expressly understood and agreed that Pharmacy is an independent contractor of Covered Entity. Nothing contained in this Agreement shall be construed to create any joint venture or other form of joint enterprise, partnership, employment or fiduciary relationship between the Parties, and neither Party shall have authority to contract for or bind the other Party in any manner whatsoever. In no event shall either Party be liable for the debts or obligations of the other, except as otherwise specifically provided in this Agreement.

9.2 Publicity. The Parties will cooperate to create appropriate public and promotional announcements or press releases relating to the relationship set forth in this Agreement. All public announcements by one Party which mention the other Party, shall be subject to prior disclosure, review, and approval by the other Party. The Party intending to make such public pronouncement must receive written consent from the other Party with respect to such disclosure, which shall not be unreasonably withheld or delayed. However, in no case may either Party disclose Confidential Information, as defined herein, in any many that conflates with the terms defining permitted disclosures as stated in this Agreement. The Parties shall be entitled, without prior consultation with or approval of the other Party, to make any press release or other public disclosure with respect to their relationship that is required by applicable law and/or regulation.

9.3 Non-Solicitation. Covered Entity recognizes that Pharmacy has valuable employment or contractual relationship with its employees, officers, and independent contractors, and Covered Entity agrees not to interfere with, disrupt, hinder, interrupt or cause harm to, those relationships. Covered Entity (and any of its respective affiliates, subsidiaries, and successors in interest) shall not, during the Term of this Agreement (as may be extended) and for one (1) year thereafter, directly or indirectly call on, solicit, employ, hire, contract with or take away, or attempt to call on, solicit, employ, hire, contract with or take away any employee, independent contractor, per diem employee, or officer of the Pharmacy. This prohibition shall apply whether such actions are taken by the Covered Entity or its agents directly or as the agent or representative of another person or entity. Pharmacy retains the right to waive this prohibition, in part or in full, upon a reasonable demand by Covered Entity in the sole discretion of Pharmacy.

9.4 Notices. All notices, requests, consents and other communications required or permitted under this Agreement shall be in writing and shall be deemed to have been given (a) upon delivery, when delivered by hand; (b) when received by the addressee if sent by a nationally recognized overnight courier (receipt requested); or (c) on the third day after the date mailed, by certified or registered mail, return receipt requested, postage prepaid. Such communications must be sent to the respective Parties at the addresses indicated below (or at such other address for a Party as shall be specified in a notice given in accordance with this Section).

To Covered Entity: County of Monterey

1270 Natividad Road

Salinas, CA 93906

ATTN: Elsa Jimenez

EMAIL: JimenezEM@co.monterey.ca.us

With Copy To:

Clinic Services Administration
1615 Bunker Hill Way, Suite 140
Salinas, CA 93906
ATTN: Contracts Monitor

To Pharmacy:

Avita Drugs, LLC
ATTN: Corporate Counsel
10604 Coursey Blvd
Baton Rouge, LA 70816
Telephone: 803-978-9068

9.5 Assignment. Neither Party may assign, transfer or delegate any or all of its rights or obligations under this Agreement without the prior written consent of the other Party.

9.6 No Third Party Beneficiaries. This Agreement is for the sole benefit of the Parties hereto and their respective successors and permitted assigns and nothing herein, express or implied, is intended to or shall confer upon any other person any legal or equitable right, benefit or remedy of any nature whatsoever, under or by reason of this Agreement.

9.7 Entire Agreement. This Agreement contains the complete, full and exclusive understanding of Covered Entity and Pharmacy with respect to the subject matter herein and supersedes any and all other oral or written agreements between the Parties hereto with respect to this subject matter.

9.8 Severability. The invalidity or unenforceability of any particular provision of this Agreement shall not affect the other provisions hereof, and this Agreement shall be construed in all respects as if such invalid or unenforceable provision were omitted.

9.9 Amendment Waiver. This Agreement may only be amended, modified or supplemented by an agreement in writing signed by the Parties. No waiver by any Party of any of the provisions hereof shall be effective unless explicitly set forth in writing and signed by the Party so waiving. Except as otherwise set forth in this Agreement, no failure to exercise, or delay in exercising, any rights, remedy, power or privilege arising from this Agreement shall operate or be construed as a waiver thereof; nor shall any single or partial exercise of any right, remedy, power or privilege hereunder preclude any other or further exercise thereof or the exercise of any other right, remedy, power or privilege.

9.10 Survival. Sections 5.4, F, G, H and I of this Agreement shall survive the termination or expiration of the Agreement regardless of the reason for such termination or expiration.

9.11 Governing Law. This Agreement shall be construed and enforced pursuant to the laws of the State of California.

9.12 Counterparts. This Agreement may be executed in any number of counterparts, each of which will be deemed to be an original, but all of which together will constitute one and the same instrument. A signed copy of this Agreement delivered by facsimile, e-mail or other means of electronic transmission shall be deemed to have the same legal effect as delivery of an original signed copy of this Agreement.

9.13 Compliance with Law. The parties shall comply with all applicable provisions of federal, state, local and other laws, ordinances and government rules and regulations, including without limitation, the Medicare and Medicaid Anti-Fraud and Abuse or Anti-Kickback Amendments to the Social Security Act (presently codified in Section 1128B(6) of the Social Security Act), the Stark Statutes codified at Section 1877 of the Social Security Act and the regulations promulgated thereunder, Section 340B, and any other laws similar to the foregoing.

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the date above.

Covered Entity:

County of Monterey

Approved as to Legal Form

BY:

DocuSigned by:

12/5/2022 | 9:29 AM PST

Stacy Satta

C0ECE1B99F444A9...

By: _____

Name: Elsa Jimenez, Director of Health

Approved as to Fiscal Provisions:

BY: Jennifer Forsyth, ACA II

DocuSigned by:

Jennifer Forsyth

12/5/2022 | 4:15 PM PST

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Pharmacy:

PMQ GROUP, LLC dba AVITA

By: *Kristen Gurley*

Name: Kristen Gurley

EXHIBIT A
PHARMACY SERVICES

A. **Covered Entity Site Information.** Contract Pharmacy will provide Pharmacy Services as outlined in the agreement for the following Covered Entity site(s):

1.1 ID: CHC33795-00
Name: County of Monterey - Laurel Pediatric Clinic

1.2 ID: CHC33795-01
Name: Monterey County Clinic at Marina

1.3 ID: CHC33795-02
Name: County of Monterey - Laurel Vista

1.4 ID: CHC33795-03
Name: County of Monterey - Laurel Internal Medicine Clinic

1.5 ID: CHC33795-04
Name: County of Monterey Integrated Health Clinic

1.6 ID: CHC33795-05
Name: County of Monterey - Laurel Family Practice Health Center

1.7 ID: CHC33795-06
Name: Alisal Health Center

1.8 ID: CHC33795-07
Name: County of Monterey - Seaside Family Health Center

1.9 ID: CHC33795-08
Name: Bienestar

1.10 ID: CHC33795-09
Name: County of Monterey - NIDO

B. Pharmacy Service Locations. Contract Pharmacy Services provided by Pharmacy pursuant to this Agreement will be provided at the following locations and any affiliate OR ANY NEWLY OPENED OR RELOCATED LOCATIONS:

- 1.1 Avita Drugs, LLC d/b/a Avita Pharmacy 1040; 5551 Corporate Blvd, Suite 102, Baton Rouge, LA 70808

- 1.2 Long's Drugs of Lexington, South Carolina, Inc. d/b/a Avita Pharmacy 1051; 1216 W. Main St., Suite D, Lexington, SC 29072

- 1.3 PharMedQuest Pharmacy Services, Inc. d/b/a Avita Pharmacy 1025; 330 E. Lamber Road #125, Brea, CA 92821

- 1.4 PharMedQuest Pharmacy Services Inc. d/b/a Avita Pharmacy 1072; 26800 Crown Valley Parkway #185, Mission Viejo, CA 92691

- 1.5

- 1.6

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- 1.10

C. Contract Pharmacy Services. In consideration for the 340B Management Fee outlined in Exhibit B, Pharmacy shall provide the following services as part of the Contract Pharmacy Services provided hereunder:

- i. Dispense Covered Drugs to Eligible Patients on behalf of Covered Entity in accordance with this Agreement and all applicable state and federal statutes and regulations.
- ii. Perform billing and collections functions to the associated third party payors on behalf of Covered Entity and perform accurate financial reporting to Covered Entity on a monthly basis.
- iii. Pharmacy agrees to attempt to collect copays, co-insurance or deductibles from Eligible Patients. Pharmacy will assist Covered Entity with coordinating copay and deductible payments from Assistance Programs, as necessary and when able, and inform Covered Entity which such Assistance Programs are applicable.
- iv. Perform billing and collections functions to the associated third party payors on behalf of Covered Entity and perform accurate financial reporting to Covered Entity on a monthly basis.
- v. Receive Covered Entity's drug inventory purchased and dispensed under the 340B Program and provide an accounting of such, as needed, to Covered Entity. Maintain an accurate inventory tracking system for all Covered Drugs, with the ability to report costs to Covered Entity at the end of each month.
- vi. Maintain all records and reports required under this Agreement, Section 340B, and any applicable federal and state law and regulations. Such records shall be retained for not less than five (5) years after the termination or expiration of this Agreement and shall be available for inspection as permitted by law and this Agreement.
- vii. Maintain Eligible Patient drug profiles. Perform adherence monitoring and drug utilization review for Eligible Patients.
- viii. Assist in the maintenance of Covered Entity's formulary, including providing drug-related information services to Covered Entity clinical personnel, and consulting with Covered Entity on the purchase of Covered Drugs.
- ix. Counsel and advise Eligible Patients on behalf of Covered Entity consistent with the rules, limitations, and privileges incident to the pharmacy-patient relationship.
- x. Provide a mechanism for Eligible Patients to dispose of medical waste products.

- xi. Make available to the Covered Entity at Pharmacy’s discretion, an Insurance Consultant to assist with patient eligibility and authorization requirements.
- xii. Create and distribute co-branded marketing materials mutually agreeable to the Parties; and provide generic sample marketing materials for Covered Entity’s consideration and implementation.

D. Purchase and Replenishment of Covered Drugs.

- i. Pharmacy will administer Covered Entity’s purchasing under Section 340B pricing for all Eligible Patients on behalf of Covered Entity.
- ii. Pharmacy will monitor its inventory to maintain sufficient supplies of drugs.
- iii. Pharmacy will perform a monthly accounting of Covered Drugs dispensed to Eligible Patients to Covered Drugs replenished on an NDC to NDC basis and forward those reports to Covered Entity in a timely manner. The monthly reports from Pharmacy shall include, at a minimum, patient name, date filled, prescription number, drug name, drug NDC, quantity, prescriber name, prescriber address, dispensing fee, tax, subtotal, 340B cost, Payer, payer adjudicated charges. Covered Entity will review the settlement and dispensing reports and perform a monthly audit to ensure 340B compliance.
- iv. Pharmacy will place replenishment wholesale orders on behalf of Covered Entity using authorized drug wholesaler accounts of Covered Entity on a scheduled basis as per Pharmacy’s need (daily, weekly, bi- monthly, or monthly).
- v. Unless indicated by the check mark below, Covered Entity will be responsible for directly paying the designated drug wholesaler for all purchases made on their accounts for Covered Drugs delivered to Pharmacy for dispensing to Eligible Patients, including Covered Drugs acquired in special purchases such as “buy forward” or “penny buy” arrangements. If elected, Pharmacy, as an agent of Covered Entity, may make payments to wholesaler for such Covered Drugs product using Covered Entity funds. Covered Entity shall enter into a “ship to, bill to” arrangement with its wholesaler and cause all shipments to be made directly to the Pharmacy. Title to Covered Drugs shall pass to Pharmacy under the “ship to, bill to” arrangement upon receipt by Pharmacy. Covered Entity shall assume responsibility for establishing all pricing for 340B Drugs. Covered Entity has adopted Pharmacy payor contract pricing for the 340B Program administered hereunder.

- Covered Entity will directly pay wholesaler(s) for orders of Covered Drugs
- Pharmacy, under agency, will make payments and place orders for Covered Drugs on behalf of Covered Entity using Covered Entity funds

- vi. Notwithstanding the foregoing, Pharmacy shall be liable for and assume all risk of any loss of or damage to drug inventory while in the possession of Pharmacy, other than loss or damage caused by Covered Entity, shipper or wholesaler. Pharmacy shall inspect inventory upon receipt and shall report damaged, missing or improperly delivered goods to wholesaler on behalf of Covered Entity. Pharmacy shall not be liable for any such reported damaged, missing or improperly delivered goods.
- vii. If a complete unit-of-use has not been dispensed within one hundred eighty (180) days of the original date dispensed or if an item dispensed is no longer available for replenishment with an identical NDC numbered drug, Pharmacy will bill Covered Entity the current Pharmacy wholesale drug cost of such drugs dispensed. There will not be an additional dispensing fee charged.
- viii. Should this Agreement expire or be terminated for any reason, Pharmacy will invoice Covered Entity the current Pharmacy wholesale drug cost for any residual non-replenished Covered Drugs with no additional dispensing fee. Such wholesale costs will be settled by a payment from Covered Entity to Pharmacy at Pharmacy's wholesale cost of the drugs at the time of purchase, invoiced to Covered Entity and paid by Covered Entity to Pharmacy within thirty (30) days from the date Covered Entity's Auditor-Controller receives the invoice as certified by Covered Entity.

EXHIBIT B
COMPENSATION

1. The following definitions shall apply for this Exhibit:

- a. "Total Adjudicated Charges" for the Contract Pharmacy Services 340B Program are defined as the total amount to be paid for all Eligible Patient prescriptions adjudicated online or submitted via HCFA 1500 or Universal Claim Form, including, but not limited to, prescriptions billed to third party, deductibles, co-insurances and co-payment amounts received from patients, the Assistance Program, and/or third party.
- b. "Total Non-Capped Adjudicated Charges" are defined as the Total Adjudicated Charges for all prescriptions except Capped Prescriptions.
- c. "Reimbursement Adjustments" are any adjustments made by a third party payor to the Total Adjudicated Charges including, but not limited to adjustments made by payors for retroactively charged fees, DIR fees, network rebates, or recoupments.
- d. "Total Adjusted Adjudicated Charges" means Total Adjudicated Charges minus known and anticipated Reimbursement Adjustments.
- e. "Generic Truvada" means all FDA-approved drugs that are approved as generic equivalents of the brand drug, Truvada.

2. As compensation for the Contract Pharmacy Services, Covered Entity will pay Pharmacy a 340B Management Fee as outlined below:

- a. Notwithstanding the foregoing, the 340B Management Fee, as defined in this section, for any given dispensing shall not be less than Fifteen Dollars (\$15) and shall not exceed Two Thousand Five Hundred Dollars (\$2,500). The prescriptions with fees capped are hereafter referred to as "Capped Prescriptions."
- b. **Dispenses for Eligible Patients Participating in Select Covered Entity Access Programs**
Covered Entity may offer select patients who are facing access or health insurance coverage affordability programs the option to enroll in Covered Entity-funded health insurance options. Specifically, this includes health insurance plans offered through the federal or state health insurance marketplaces offered under the Affordable Care Act. Covered Entities may engage with select Third-Parties to facilitate this enrollment and fund patient premium costs using 340B proceeds when allowed by law, regulation and/or grant language.

To offset and minimize the financial impact to Covered Entities who elect to offer and help patients by enrolling them in these access and affordability programs and paying the patient premiums on their behalf by using the Covered Entity's 340B Proceeds, Avita may cap the 340B Management Fee for select dispenses for patients actively enrolled in such programs (Capped Prescriptions). Only Eligible Patients and Eligible Dispenses using select 340B Drugs will be eligible for a capped fee under this program.

- i. Eligible Dispenses:
To be eligible, a dispensing must be of one of the following 340B Drugs:
 - o Tier 1
 - Descovy
 - Truvada
- ii. Capped 340B Management Fee:
The 340B Management Fee for Eligible Dispenses to Eligible Patients shall be:
 - a. For dispenses of Tier 1 Eligible Dispenses, \$225
- c. For All Other Prescriptions, the applicable 340B Management Fee shall be:
 - i. The applicable fee for All Other Prescriptions is applied based on the dollar value of Total Non-Capped Adjudicated Charges
 - ii. If the Total Non-Capped Adjudicated Charges for All Other Prescriptions and for Generic Truvada are less than One Million Two Hundred Fifty Thousand Dollars (\$1,250,000) for each of the previous three (3) consecutive months then the 340B Management Fee shall be Eighteen Percent (18%) of Total Adjusted Adjudicated Charges for All Other Prescriptions in the current period.
 - iii. If the Total Non-Capped Adjudicated Charges for All Other Prescriptions and for Generic Truvada for each of the previous three (3) consecutive months exceeds One Million Two Hundred Fifty Thousand Dollars (\$1,250,000) for each of the previous three (3) consecutive months then the 340B Management Fee shall be Seventeen Percent (17%) of Total Adjusted Adjudicated Charges for All Other Prescriptions in the current period.
 - iv. If the Total Non-Capped Adjudicated Charges for each of the previous three consecutive months exceeds One Million Seven Hundred Fifty Thousand Dollars (\$1,750,000) then the 340B Management Fee shall be Sixteen Percent (16%) of Total Adjusted Adjudicated Charges in the current period.
 - v. For purposes of determining which 340B Management Fee tier shall apply each month, the Total Non-Capped Adjudicated Charges in the prior three months will each be viewed independently, not averaged. The target has to be met in each of the three months for the decreased fee to apply.
- d. Prescriptions written for PrEP by Telemedicine Providers ("TelePrEP"):
 - i. TelePrEP Prescriptions will not be subject to the tiered percentage structure outlined in subsection c. The total adjusted non-capped adjudicated charges of TelePrEP prescriptions will be subject to a Twelve Percent ("12%") 340B management fee.

- f. Insured prescriptions resulting in negative net proceeds are removed from the program to maximize cost savings benefits
 - g. A “Dispensing Fee” equal to Fifteen Dollars (\$15) per prescriptions for prescriptions dispensing to Eligible Patients who have no third-party coverage (such as Medicare or private insurance)
3. Within twenty (20) business days after the end of each month, the Pharmacy shall provide Covered Entity with an invoice detailing the Total Adjusted Adjudicated Charges, the 340B Management Fee, and any Dispensing Fees owed for the prior month, along with estimated amounts needed for payment to the wholesalers for 340B Drug replenishment.
 4. The Covered Entity agrees to pay to Pharmacy all copays, co-insurance, or deductibles due from its Eligible Patients and collected by Covered Entity. Pharmacy shall detail such amounts due on the invoice detailed in Section 3 above. Covered Entity agrees that Pharmacy may deduct the total amount of copays due from Eligible Patients from any amounts due to Covered Entity as provided below. Covered Entity agrees to maintain all records regarding the collection of copays, co-insurance, or deductibles for at least 5 years and to remit the original or certified copies of such records to Pharmacy within 10 business dates of Pharmacy making a request for such.
 5. The Pharmacy shall remit the net amount of Total Adjudicated Charges minus earned fees (340B Management Fee plus Dispensing Fees) minus copays minus any drug cost to be replenished by check or bank transfer to Covered Entity either (i) concurrently with the provision of the invoice described above, or (ii) within twenty-four (24) business hours once pharmacy has received replenishment drug order.
 6. The pharmacy will remit the drug cost to the Covered Entity no later than forty-eight (48) business hours before the drug replenishment invoices are due for payment to wholesaler via check or bank transfer.

Exhibit C: Delivery Addendum

**(NOT APPLICABLE UNLESS EXPANDED DELIVERY SERVICES
ARE AGREED TO BY BOTH PARTIES)**

In addition to the parties' rights and obligations under this Agreement, should the Parties agree to provide for the delivery of 340B Covered Drugs to a patient or their representative via a common carrier or courier, the Parties agree as follows:

1. Delivery

- 1.1 Pharmacy shall provide for the delivery of 340B Covered Drugs to those patients of Covered Entity who request such service.
- 1.2 The delivery of 340B Covered Drugs shall be to the patient's current address as provided to Pharmacy by the Covered Entity, the patient, or their duly appointed representative.
- 1.3 340B Covered Drugs shall be delivered to patient by a means selected by Pharmacy. This may include by courier, a Pharmacy employee, a common carrier, or other local delivery service retained by Pharmacy. Choice of delivery method shall be at the sole discretion of Pharmacy and may change at any time, with or without notice to the Covered Entity or patient.
- 1.4 Pharmacy will not be responsible for any damages to or loss of 340B Covered Drugs caused by or on account of the actions of the courier or delivery service. Such liability will be governed in accordance with any contracts or other agreements executed by and between Pharmacy and such delivery service. Pharmacy may agree, at Pharmacy's sole discretion, to provide copies of any such delivery agreements to Covered Entity upon request.
- 1.5 As may be permitted according to federal, state, local, and/or payer statute, regulations or guidance, neither patients nor their permitted representatives will be required to sign a "proof of delivery" log to confirm receipt. In lieu of such signature and as proof of delivery, Pharmacy or their delivery representative may provide:
 - 1.5.1 Notation by the Delivery Service Provider of the date, time, and name of person who is receiving the medication, or
 - 1.5.2 Delivery Service Provider's confirmation or receipt of delivery.
- 1.6 Records of delivery shall be maintained in the same manner and for the same duration as other proof of delivery and documentation requirements that may apply concerning the discharging of Pharmacy Services in the pharmacy setting.

2. Fees

- 2.1 Covered Entity understands and the Parties agree that the cost for delivery services are above and beyond the Professional Fees outlined in **Exhibit A** of

the Agreement. Covered Entity agrees to reimburse Pharmacy for any and all costs reasonably incurred by PMQ related to the establishment, maintenance, and execution of any delivery services. Pharmacy will, however, not charge Covered Entity for shipping of 340B Covered Drugs to Eligible Patients where the actual cost of shipping such Covered Drugs does not exceed \$3.50 per shipment.

- 2.2 Pharmacy reserves the right to take reimbursement for delivery services by deducting amounts due from the Covered Entity under this Addendum from any revenue payable to Covered Entity and based on the current agreed fee structure under this Agreement.
- 2.3 The amount of any fees for delivery services will be reflected on Covered Entity's invoice/EOB.
- 2.4 Covered Entity understands that costs for delivery services may be subject to change at any time, with or without notice, and may differ depending on the nature and conditions of the delivery made or to be made. Pharmacy will endeavor to notify CLIENT of any material increases in cost that would represent more than a 20% change in per delivery fees.
- 2.5 Payment is due from the Covered Entity under the same timeline and subject to the same terms and conditions as control for other services rendered under pursuant to Exhibit B of this Agreement.

[SIGNATURES ON NEXT PAGE]

In Witness Whereof, this Addendum is executed by the Parties effective as of the Effective Date.

Covered Entity: County of Monterey

Business Associate: PMQ Group LLC dba Avita

Signature: _____

Signature: Kristen Gurley

Printed Name: Elsa Jimenez, Director of Health

Printed Name: Kristen Gurley

Title: _____

Title: Regulatory Counsel

BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement (“BAA”) effective January 1, 2023 (“Effective Date”), is entered into by and among between the County of Monterey, a political subdivision of the State of California, on behalf of the Health Department (“Covered Entity”) and PMQ Group, LLC dba Avita, on behalf of its subsidiaries (“Business Associate”) (each a “Party” and collectively the “Parties”).

RECITALS

A. WHEREAS, Business Associate provides certain services for Covered Entity that involve the Use and Disclosure of Protected Health Information (“PHI”) that is created, received, transmitted, or maintained by Business Associate for or on behalf of Covered Entity.

B. WHEREAS, the Parties are committed to complying with the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (the “HITECH Act”), and their implementing regulations, including the Standards for the Privacy of Individually Identifiable Health Information, 45 C.F.R. Part 160 and Part 164, subparts A and E (the “Privacy Rule”), the Breach Notification Standards, 45 C.F.R. Part 160 and 164 subparts A and D (the “Breach Notification Rule”), and the Security Standards for the Protection of Electronic Protected Health Information, 45 C.F.R. Part 160 and Part 164, subparts A and C (the “Security Rule”) (collectively “HIPAA”), all as amended from time to time.

C. WHEREAS, the Parties are also committed to complying with the California Confidentiality Laws (defined below).

D. WHEREAS, to the extent that Business Associate is performing activities in connection with covered accounts for or on behalf of Covered Entity, the Parties are also committed to complying with applicable requirements of the Red Flag Rules issued pursuant to the Fair and Accurate Credit Transactions Act of 2003 (“Red Flag Rules”).

E. WHEREAS, the Privacy and Security Rules require Covered Entity and Business Associate to enter into a business associate agreement that meets certain requirements with respect to the Use and Disclosure of PHI. This BAA sets forth the terms and conditions pursuant to which PHI, and, when applicable, Electronic Protected Health Information (“EPHI”) shall be handled, in accordance with such requirements.

NOW THEREFORE, in consideration of the mutual promises below and the exchange of information pursuant to this BAA, the Parties agree as follows:

AGREEMENT

DEFINITIONS

All capitalized terms used in this BAA but not otherwise defined shall have the meaning set forth in HIPAA.

(a) “Breach” shall have the same meaning as “breach” as defined in 45 C.F.R. § 164.402; however, the term “Breach” as used in this BAA shall also mean the unlawful or unauthorized access to, Use or Disclosure of a patient’s “medical information” as defined under Cal. Civil Code § 56.05(j), for which notification is required pursuant to Cal. Health & Safety Code 1280.15, or a “breach of the security of the system” under Cal. Civil Code § 1798.29.

(b) “California Confidentiality Laws” shall mean the applicable laws of the State of California governing the confidentiality, privacy, or security of PHI or other personally identifiable information (PII), including, but not limited to, the California Confidentiality of Medical Information Act (Cal. Civil Code § 56 *et seq.*), the patient access law (Cal. Health & Safety Code § 123100 *et seq.*), the HIV test result confidentiality law (Cal. Health & Safety Code § 120975 *et seq.*), the Lanterman-Petris-Short Act (Cal. Welf. & Inst. Code § 5328 *et seq.*), and California’s data breach law (Cal. Civil Code § 1798.29).

(c) “Protected Health Information” or “PHI” shall mean any information, whether oral or recorded in any form or medium: (i) that relates to the past, present or future physical or mental condition of an individual; the provision of health care to an individual or the past, present or future payment for the provision of health care to an individual; (ii) that identifies the individual or with respect to which there is a reasonable basis to believe the information that can be used to identify the individual, and (iii) is provided by Covered Entity to Business Associate or created, maintained, received, or transmitted by Business Associate on Covered Entity’s behalf. PHI, when used in this BAA, includes EPHI.

(d) “Services” shall mean the services for or functions performed by Business Associate on behalf of Covered Entity pursuant to an underlying services agreement “(Services Agreement)” between Covered Entity and Business Associate to which this BAA applies.

PERMITTED USES AND DISCLOSURES OF PHI

Unless otherwise limited herein, Business Associate may:

(a) Use or Disclose PHI to perform Services for, or on behalf of, Covered Entity, provided that such Use or Disclosure would not violate the Privacy or Security Rules, this BAA, or California Confidentiality Laws if done by Covered Entity;

(b) Use PHI to provide Data Aggregation Services for the Health Care Operations of Covered Entity, if required by the Services Agreement and as permitted by 45 C.F.R. § 164.504(e)(2)(i)(B);

(c) Use PHI if necessary for the proper management and administration of Business Associate or to carry out the legal responsibilities of Business Associate as permitted by 45 C.F.R. § 164.504(e)(4)(i);

(d) Disclose PHI for the proper management and administration of Business Associate or to carry out the legal responsibilities of Business Associate as permitted under 45 C.F.R. § 164.504(e)(4)(ii), provided that Disclosures are Required by Law, or Business Associate obtains reasonable assurances from the person to whom the information is Disclosed that it will remain confidential and be Used or further Disclosed only as Required by Law or for the purpose for which it was Disclosed to the person, and that such person will notify the Business Associate of any instances of which such person is aware that the confidentiality of the information has been breached; and

(e) Use PHI to report violations of law to appropriate Federal and state authorities, consistent with 45 C.F.R. § 164.502(j)(1).

RESPONSIBILITIES OF THE PARTIES WITH RESPECT TO PHI

3.1. Responsibilities of Business Associate. Business Associate shall:

(a) Notify the Privacy Officer of Covered Entity, in writing, of: (i) any Use and/or Disclosure of the PHI that is not permitted by this BAA; (ii) any Security Incident of which Business Associate becomes aware; and (iii) any suspected Breach. Such notice shall be provided within five (5) business days of Business Associate's discovery of such unauthorized access, acquisition, Use and/or Disclosure, Security Incident, or suspected Breach. Notwithstanding the foregoing, the Parties acknowledge the ongoing existence and occurrence of attempted but ineffective Security Incidents that are trivial in nature, such as pings and other broadcast service attacks, and unsuccessful log-in attempts. The Parties acknowledge and agree that this Section 3.1(a) constitutes notice by Business Associate to Covered Entity of such ineffective Security Incidents and no additional notification to Covered Entity of such ineffective Security Incidents is required, provided that no such Security Incident results in unauthorized access, acquisition, Use or Disclosure of PHI. For the avoidance of doubt, a ransomware attack shall not be considered an ineffective Security Incident and shall be reported to Covered Entity, irrespective of whether such Security Incident results in a Breach. Business Associate shall investigate each Security Incident or unauthorized access, acquisition, Use, or Disclosure of PHI, or suspected Breach that it discovers and shall provide a summary of its investigation to Covered Entity, upon request.

(i) If Business Associate or Covered Entity determines that such Security Incident or unauthorized access, acquisition, Use, or Disclosure, or suspected Breach constitutes a Breach, then Business Associate shall provide a supplemental written report in accordance with 45 C.F.R. § 164.410(c), which shall include, to the extent possible, the identification of each individual whose PHI has been, or is reasonably believed by the Business Associate to have been, accessed, acquired, Used or Disclosed during the Breach, to Covered Entity without unreasonable delay, but no later than five (5) business days after discovery of the Breach;

(ii) In consultation with Covered Entity, Business Associate shall promptly mitigate, to the extent practicable, any harmful effect that is known to the Business Associate of such improper access, acquisition, Use, or Disclosure, Security Incident, or Breach;

(iii) Covered Entity shall have sole control over the timing and method of providing notification of such Breach to the affected individual(s), the appropriate government agencies, and other persons required by law to be notified. Business Associate shall assist with any notifications, as requested by Covered Entity. Business Associate shall take prompt corrective action, including any action required by applicable State or federal laws and regulations relating to such Security Incident or non-permitted access, acquisition, Use, or Disclosure. Business Associate shall reimburse Covered Entity for its reasonable costs and expenses in providing notification to affected individuals, appropriate government agencies, and any other persons required by law to be notified (e.g., without limitation, the media or consumer reporting agencies), including, but not limited to, any administrative costs associated with providing notice, printing and mailing costs, public relations costs, attorney fees, and costs of mitigating the harm (which may include the costs of obtaining up to one (1) year of credit monitoring services and identity theft insurance) for affected individuals whose PHI or other PII has or may have been compromised as a result of the Breach;

(b) Implement appropriate administrative, physical, and technical safeguards and comply with the Security Rule and industry best practices to prevent Use and/or Disclosure of EPHI other than as provided for by this BAA;

(c) Obtain and maintain a written agreement with each of its Subcontractors that creates, receives, maintains, or transmits PHI that requires each such Subcontractor to adhere to restrictions and conditions

that are at least as restrictive as those that apply to Business Associate pursuant to this BAA. Upon request, Business Associate shall provide Covered Entity with copies of its written agreements with such Subcontractors;

(d) Make available all internal practices, records, books, agreements, policies and procedures and PHI relating to the Use and/or Disclosure of PHI received from, created, maintained, or transmitted by Business Associate on behalf of Covered Entity to the Secretary of the Department of Health and Human Services ("Secretary") in a time and manner designated by the Secretary for purposes of determining Covered Entity's or Business Associate's compliance with HIPAA. Business Associate shall immediately notify Covered Entity of any such requests by the Secretary and, upon Covered Entity's request, provide Covered Entity with any copies of documents Business Associate provided to the Secretary. In addition, Business Associate shall promptly make available to Covered Entity such practices, records, books, agreements, policies and procedures relating to the Use and Disclosure of PHI for purposes of determining whether Business Associate has complied with this BAA or maintains adequate security safeguards, upon reasonable request by Covered Entity. The fact that Covered Entity has the right to inspect, inspects, or fails to inspect Business Associate's internal practices, records, books, agreements, policies and procedures does not relieve Business Associate of its responsibility to comply with this BAA, regardless of whether Covered Entity detects or fails to detect a violation by Business Associate, nor does it constitute Covered Entity's acceptance of such practices or waiver of Covered Entity's rights under this BAA;

(e) Document Disclosures of PHI and information related to such Disclosure and, within twenty (20) days of receiving a written request from Covered Entity, provide to Covered Entity such information as is requested by Covered Entity to permit Covered Entity to respond to a request by an individual for an accounting of the Disclosures of the individual's PHI in accordance with 45 C.F.R. § 164.528 and the HITECH Act. At a minimum, the Business Associate shall provide Covered Entity with the following information: (i) the date of the Disclosure; (ii) the name of the entity or person who received the PHI, and if known, the address of such entity or person; (iii) a brief description of the PHI Disclosed; and (iv) a brief statement of the purpose of such Disclosure which includes an explanation of the basis for such Disclosure. In the event the request for an accounting is delivered directly to the Business Associate, the Business Associate shall, within ten (10) days, forward such request to Covered Entity. The Business Associate shall implement an appropriate recordkeeping process to enable it to comply with the requirements of this Section;

(f) Subject to Section 4.4 below, return to Covered Entity in a mutually agreeable format and medium, or destroy, within thirty (30) days of the termination of this BAA, the PHI in its possession and retain no copies, including backup copies;

(g) Use, Disclose to its Subcontractors or other third parties, and request from Covered Entity, only the minimum PHI necessary to perform or fulfill a specific function required or permitted hereunder;

(h) If all or any portion of the PHI is maintained in a Designated Record Set:

(i) Upon ten (10) days' prior written request from Covered Entity, provide access to the PHI to Covered Entity, or to the individual, if so directed by Covered Entity, to meet a request by an individual under 45 C.F.R. § 164.524 or California Confidentiality Laws. Business Associate shall notify Covered Entity within five (5) days of its receipt of a request for access to PHI from an individual; and

(ii) Upon ten (10) days' prior written request from Covered Entity, make any amendment(s) to the PHI that Covered Entity directs pursuant to 45 C.F.R. § 164.526. Business Associate shall notify Covered Entity within five (5) days of its receipt of a request for amendment of PHI from an individual;

(i) If applicable, maintain policies and procedures to detect and prevent identity theft in connection with the provision of the Services, to the extent required to comply with the Red Flag Rules;

(j) To the extent that Business Associate carries out one or more of Covered Entity's obligations under the Privacy Rule, Business Associate shall comply with the requirements of the Privacy Rule that apply to Covered Entity in the performance of such obligations;

(k) Unless prohibited by law, notify Covered Entity as soon as possible and in no case later than five (5) days after the Business Associate's receipt of any request or subpoena for PHI. To the extent that Covered Entity decides to assume responsibility for challenging the validity of such request, the Business Associate shall cooperate fully with Covered Entity in such challenge; and

(l) Maintain policies and procedures materially in accordance with HIPAA and California Confidentiality Laws and industry standards designed to ensure the confidentiality, availability, and integrity of Covered Entity's data and protect against threats or vulnerabilities to such data.

3.2 Business Associate Acknowledgment.

(a) Business Associate acknowledges that, as between the Business Associate and Covered Entity, all PHI shall be and remain the sole property of Covered Entity.

(b) Business Associate is not permitted to Use PHI to create de-identified information except as approved in writing by Covered Entity.

(c) Business Associate further acknowledges that it is obligated by law to comply, and represents and warrants that it shall comply, with HIPAA. Business Associate shall comply with all California Confidentiality Laws, to the extent that such state laws are not preempted by HIPAA.

(d) Business Associate further acknowledges that Uses and Disclosures of PHI must be consistent with Covered Entity's privacy practices, as stated in Covered Entity's Notice of Privacy Practices. The current Notice of Privacy Practices can be retrieved online from the Covered Entity's webpage. Business Associate agrees to review the Notice of Privacy Practices at this URL at least once annually while doing business with Covered Entity to ensure it remains updated on any changes to the Notice of Privacy Practices Covered Entity may make.

3.3 Responsibilities of Covered Entity. Covered Entity shall notify Business Associate of any (i) changes in, or withdrawal of, the authorization of an individual regarding the Use or Disclosure of PHI provided to Covered Entity pursuant to 45 C.F.R. § 164.508, to the extent that such changes may affect Business Associate's Use or Disclosure of PHI; or (ii) restrictions on Use and/or Disclosure of PHI as provided for in 45 C.F.R. § 164.522 agreed to by Covered Entity, to the extent that such restriction may affect Business Associate's Use or Disclosure of PHI.

TERM AND TERMINATION

4.1 Term. This BAA shall become effective on the Effective Date and shall continue in effect until all of the PHI provided by Covered Entity to Business Associate, or created or received by Business Associate on behalf of Covered Entity, is destroyed or returned to Covered Entity, or if it is infeasible to return or destroy PHI, protections are extended to such PHI, in accordance with the termination provisions in Section 4.4. Certain

provisions and requirements of this BAA shall survive its expiration or other termination as set forth in Section 5 herein.

4.2 Termination. If Covered Entity determines in good faith that Business Associate has breached a material term of this BAA, Covered Entity may either: (i) immediately terminate this BAA and any underlying Services Agreement without penalty; or (ii) terminate this BAA and any underlying Services Agreement within thirty (30) days of Business Associate's receipt of written notice of such breach, if the breach is not cured to the satisfaction of Covered Entity.

4.3 Automatic Termination. This BAA shall automatically terminate without any further action of the Parties upon the termination or expiration of all Services Agreements between Covered Entity and Business Associate that would necessitate having this BAA in place.

4.4 Effect of Termination. Upon termination or expiration of this BAA for any reason, Business Associate shall return or destroy all PHI pursuant to 45 C.F.R. § 164.504(e)(2)(ii)(J) if, and to the extent that, it is feasible to do so. Prior to returning or destroying the PHI, Business Associate shall recover any PHI in the possession of its Subcontractors. Business Associate shall certify in writing that all PHI has been returned or securely destroyed, and no copies retained, upon Covered Entity's request. To the extent it is not feasible for Business Associate to return or destroy any portion of the PHI, Business Associate shall notify Covered Entity in writing of the condition that makes return or destruction infeasible. If Covered Entity agrees that return or destruction of the PHI is infeasible, as determined in its sole discretion, Business Associate shall: (i) retain only that PHI which is infeasible to return or destroy; (ii) return to Covered Entity the remaining PHI that the Business Associate maintains in any form; (iii) continue to extend the protections of this BAA to the PHI for as long as Business Associate retains PHI; (iv) limit further Uses and Disclosures of such PHI to those purposes that make the return or destruction of the PHI not feasible and subject to the same conditions as set out in Sections 2 and 3 above, which applied prior to termination; and (v) return to Covered Entity the PHI retained by Business Associate when such return is no longer infeasible.

MISCELLANEOUS

5.1 Survival. The obligations of Business Associate under the provisions of Sections 3.1, 3.2, and 4.4 and Article 5 shall survive termination of this BAA until such time as all PHI is returned to Covered Entity or destroyed.

5.2 Amendments; Waiver. This BAA may not be modified or amended, except in a writing duly signed by authorized representatives of the Parties. To the extent that any relevant provision of HIPAA or California Confidentiality Laws is materially amended in a manner that changes the obligations of the Parties, the Parties agree to negotiate in good faith appropriate amendment(s) to this BAA to give effect to the revised obligations. Further, no provision of this BAA shall be waived, except in a writing duly signed by authorized representatives of the Parties. A waiver with respect to one event shall not be construed as continuing, or as a bar to or waiver of any right or remedy as to subsequent events.

5.3 No Third Party Beneficiaries. Nothing express or implied in this BAA is intended to confer, nor shall anything herein confer, upon any person other than the Parties and the respective successors or assigns of the Parties, any rights, remedies, obligations, or liabilities whatsoever.

5.4 Notices. Any notices to be given hereunder to a Party shall be made via U.S. Mail or express courier to such Party's address given below, and/or via facsimile or email to the facsimile telephone numbers or email addresses listed below.

If to Business Associate, to:

PMQ Group, LLC dba Avita
Attn: Chief Compliance and Privacy Officer
10604 Coursey Blvd.
Baton Rouge, LA 70816
Phone: (844)319-0646
Fax: (866)550-7461
Email: compliance@avitapharmacy.com

If to Covered Entity, to:

County of Monterey Health Department
Attn: Compliance/Privacy Officer
1270 Natividad Road
Salinas, CA 93906
Phone: 831-755-4018
Email: sumeshwarsd@co.monterey.ca.us

Each Party named above may change its address and that of its representative for notice by the giving of notice thereof in the manner hereinabove provided. Such notice is effective upon receipt of notice, but receipt is deemed to occur on next business day if notice is sent by FedEx or other overnight delivery service.

5.5 Counterparts; Facsimiles. This BAA may be executed in any number of counterparts, each of which shall be deemed an original. Facsimile and electronic copies hereof shall be deemed to be originals.

5.6 Relationship of Parties. Notwithstanding anything to the contrary in the Services Agreement, Business Associate is an independent contractor and not an agent of Covered Entity under this BAA. Business Associate has the sole right and obligation to supervise, manage, contract, direct, procure, perform, or cause to be performed all Business Associate obligations under this BAA.

5.7 Choice of Law; Interpretation. This BAA shall be governed by the laws of the State of California. Any ambiguities in this BAA shall be resolved in a manner that allows Covered Entity and Business Associate to comply with HIPAA and the California Confidentiality Laws.

5.8 Indemnification. Business Associate shall indemnify, defend, and hold harmless the County of Monterey (the "County"), its officers, agents, and employees from any claim, liability, loss, injury, cost, expense, penalty or damage, including costs incurred by the County with respect to any investigation, enforcement proceeding, or third party action, arising out of, or in connection with, a violation of this BAA, HIPAA or California Confidentiality Laws, or a Breach that is attributable to an act or omission of Business Associate and/or its agents, members, employees, or Subcontractors, excepting only loss, injury, cost, expense, penalty or damage caused by the negligence or willful misconduct of personnel employed by the County. It is the intent of the Parties to provide the broadest possible indemnification for the County. This provision is in addition to, and independent of, any indemnification provision in any Services Agreement between the Parties.

5.9 Applicability of Terms. This BAA applies to all present and future Services Agreements and business associate relationships, written or unwritten, formal or informal, in which Business Associate creates, receives, transmits, or maintains any PHI for or on behalf of Covered Entity in any form whatsoever. This BAA shall automatically be incorporated in all subsequent agreements between Business Associate and Covered Entity

involving the Use or Disclosure of PHI whether or not specifically referenced therein. In the event of any conflict or inconsistency between a provision of this BAA and a provision of any other agreement between Business Associate and Covered Entity, the provision of this BAA shall control unless the provision in such other agreement establishes additional rights for Business Associate or additional duties for or restrictions on Business Associate with respect to PHI, in which case the provision of such other agreement will control.

5.10 Insurance. In addition to any general and/or professional liability insurance required of Business Associate under the Services Agreement, Business Associate agrees to obtain and maintain, at its sole expense, liability insurance on an occurrence basis, covering any and all claims, liabilities, demands, damages, losses, costs expenses, fines, and compliance costs arising from a breach of the obligations of Business Associate, its officers, employees, agents and Subcontractors under this BAA. Without limiting the foregoing, at a minimum, Business Associate's required insurance under this Section shall include cyber liability insurance covering breach notification expenses, network security and privacy liability, with limits of not less than \$10,000,000 per claim and in the aggregate. Such insurance coverage will be maintained for the term of this BAA, and a copy of such policy or a certificate evidencing the policy shall be provided to Covered Entity at Covered Entity's request.

5.11 Legal Actions. Promptly, but no later than five (5) calendar days after notice thereof, Business Associate shall advise Covered Entity of any actual or potential action, proceeding, regulatory or governmental orders or actions, or any material threat thereof that becomes known to it that may affect the interests of Covered Entity or jeopardize this BAA, and of any facts and circumstances that may be pertinent to the prosecution or defense of any such actual or potential legal action or proceeding, except to the extent prohibited by law. This includes, without limitation, any allegation that Business Associate has violated HIPAA or other federal or state privacy or security laws.

5.12 Audit or Investigations. Promptly, but no later than five (5) calendar days after notice thereof, Business Associate shall advise Covered Entity of any audit, compliance review, or complaint investigation by the Secretary or other state or federal agency related to compliance with HIPAA or the California Confidentiality Laws.


5.13 Assistance in Litigation or Administrative Proceedings. Business Associate shall make itself, and any Subcontractors, employees, or agents assisting Business Associate in the performance of its obligations under any Services Agreements, available to Covered Entity, at no cost to Covered Entity, to testify in any claim commenced against Covered Entity, its directors, officers, employees, successors, and assigns based upon claimed violation by Business Associate or its agents or subcontractors of HIPAA or other applicable law, except where Business Associate or its Subcontractor, employee, or agent is a named adverse party.

5.14 No Offshore Work. In performing the Services for, or on behalf of, Covered Entity, Business Associate shall not, and shall not permit any of its Subcontractors, to transmit or make available any PHI to any entity or individual outside the United States without the prior written consent of Covered Entity.

5.15 Information Blocking Rules. Business Associate shall not take any action, or refuse to take any action, with regard to Covered Entity's electronic health information that would result in "information blocking" as prohibited by 42 U.S.C. § 300jj-52 and 45 C.F.R. Part 171 (collectively, "Information Blocking Rules"). Business Associate and Covered Entity shall cooperate in good faith to ensure Covered Entity's electronic health information is accessed, exchanged, and used in compliance with the Information Blocking Rules.

IN WITNESS WHEREOF, each of the undersigned has caused this BAA to be duly executed in its name and on its behalf as of the Effective Date.

BUSINESS ASSOCIATE

By: 

Print Name: Kristen Gurley

Title: Regulatory Counsel

Date: 11/18/2022

COVERED ENTITY

By: _____

Print Name: _____

Title: _____

Date: _____